K070217

Section 5 - 510(k) Summary

APR - 4 2008

Submitter Information
Neuro Resource Group, Inc.
1100 Jupiter Road, Suite 190
Plano, TX 75074
Establishment Registration # 3004786509

Contact
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Date Prepared
April 3, 2008

Product Name
InterX 1000/Derma 200 Stimulator for Cosmetic Use

Predicate Devices

Device	Manufacturer	510k Reference
InterX 5000	Neuro Resource Group	K042912
Rejuvenique	Salton	K011935
Facemaster	Facemaster of Beverly Hills	K040871

Product Description
The InterX 1000/Derma 200 Stimulator for Cosmetic Use is a hand-held, battery operated device consisting of a main operating unit (InterX 1000) and an external electrode (Derma 200).

Intended Use
This device is intended for cosmetic use.

Comparison to Predicate Device
This device is equivalent in technology to the InterX 5000 device, currently marketed by our firm under K042912, with changes to accommodate new indications for cosmetic use. These indications are equivalent to devices cleared under K040871 and K011935.

Performance Testing & Conclusions
This device complies with performance standard requirements (21 CFR 898.12) relating to patient lead wires and electrodes. Bench and clinical testing were conducted to demonstrate performance for the device's intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Neuro Resource Group, Inc.
% Ms. Krista Oakes
Vice President, Regulatory Affairs
1100 Jupiter Road, Suite 190
Plano, Texas 75074

APR - 4 2008

Re: K070217
Trade Name: InterX 1000 Stimulator/Derma 200 Electrode for Cosmetic Use
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code NFO, GXY
Dated: January 4, 2008
Received: January 7, 2008

Dear Ms. Oakes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: InterX 1000/Derma 200 Stimulator for Cosmetic Use

Indications for Use:

This device is intended for cosmetic use.

Prescription Use ___XX____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070217